

DEC 21 2004

K042000

**Attachment 25 – 510(k) Summary for the Modified MSq Family of Lovely Light/Laser System Handpieces**

**I. General Information**

Submitter: MSq (M<sup>2</sup>) Ltd.  
7 Haeshel Street, POB 3021  
Caesarea Industrial Park 38900, Israel

Contact Person: Anne C Worden  
Regulatory Consultant

Summary Preparation Date: July 21, 2004

**II. Names**

Device Names: Modified MSq Family of Lovely Light/Laser System,  
Delivery Devices and Accessories

Primary Classification Names: Surgical Powered Laser Instrument and Ultraviolet  
Dermatological Light

**III. Predicate Devices**

- MSq Family of Lovely Light/Laser Systems (K033946)
- Lumenis BClear Targeted PhotoClearing System (K021762)
- Innotech USA The FriendlyLight Nd:YAG Laser (K033251)
- Cutera Family of CoolGlide Lasers (K023954)
- Palomar Clear Light™ Nd:YAG Laser System (K003460)
- Candela GentleYAG Family of Laser Systems (K033172)
- Coherent Medical VersaPulse Aesthetic Surgical Lasers (K972347)
- Hoya-ConBio Medlite C6 / C3 Q-Switched Nd:YAG Lasers (K014234)
- Hoya-ConBio Medlite Q-Switched Laser (K022709)
- Sciton Profile 1320 Laser System (K032459)
- New Star Lasers CoolTouch 3, CT3, and II Lasers (K031184, K031954, and K030453)
- New Star Lasers CoolTouch II and CT3 Nd:YAG Lasers (K040131)
- Cynosure TriStar Aesthetic Workstation (K033176)
- Laserscope Venus I, EL and Vela Er:YAG lasers (K974896, K971843 and Other Laserscope Er:YAG Laser Clearances)
- Innotech USA FriendlyLight Er:YAG Pulsed Laser (K000023)
- Sciton Profile-S and 3000 Er:YAG Laser Systems (K040005 & K010285)

**IV. Product Description**

The modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories are comprised of the following main components:

- A system console that includes the control display, software and control electronics, keyswitch, emergency stop, cooling system, optics bench;
- Footswitch;
- Variety of handpieces and attachment accessories.

#### **V. Indications for Use**

The modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories are indicated for a variety of aesthetic and surgical applications in the medical specialties of general and plastic surgery and dermatology, endoscopic/ laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology.

#### **VI. Rationale for Substantial Equivalence**

The modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories share the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore are substantially equivalent for use in general and plastic surgery and dermatology, endoscopic/ laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications to the predicate MSq Family of Lovely Light/Laser Systems (K033946), as well as to the Lumenis BClear Targeted PhotoClearing System (K021762), Innotech The FriendlyLight Nd:YAG Laser (K033251), the Cutera Family of CoolGlide Lasers (K023954), the Palomar Clear Light™ Nd:YAG Laser System (K003460), the Candela GentleYAG Family of Laser Systems (K033172), the Coherent Medical VersaPulse Aesthetic Surgical Lasers (K972347), the Hoya-ConBio Medlite C6 / C3 Q-Switched Nd:YAG Lasers (K014234), the Hoya-ConBio Medlite Q-Switched Laser (K022709), the Sciton Profile 1320 Laser System (K032459), the New Star Lasers CoolTouch 3, CT3, and II Lasers (K031184, K031954, and K030453), the New Star Lasers CoolTouch II and CT3 Nd:YAG Lasers (K040131), the Cynosure TriStar Aesthetic Workstation (K033176), the predicate Venus I, EL and Vela Er:YAG lasers manufactured by Laserscope (K974896, K971843 and other Laserscope Er:YAG laser clearances), the predicate FriendlyLight Er:YAG Pulsed Laser manufactured by Innotech USA (K000023), and the predicate Sciton Profile-S and 3000 Er:YAG Laser Systems (K040005 & K010285).

#### **VII. Safety and Effectiveness Information**

The review of the indications for use and technical characteristics provided to demonstrate that the modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories are substantially equivalent to the predicate devices.

#### **VIII. Conclusion**

The modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories was found to be substantially equivalent to the predicate MSq Family of Lovely Light/Laser Systems (K033946), as well as to the Lumenis BClear Targeted PhotoClearing System (K021762), Innotech The FriendlyLight Nd:YAG Laser

K040000

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(K033251), the Cutera Family of CoolGlide Lasers (K023954), the Palomar Clear Light™ Nd:YAG Laser System (K003460), the Candela GentleYAG Family of Laser Systems (K033172), the Coherent Medical VersaPulse Aesthetic Surgical Lasers (K972347), the Hoya-ConBio Medlite C6 / C3 Q-Switched Nd:YAG Lasers (K014234), the Hoya-ConBio Medlite Q-Switched Laser (K022709), the Sciton Profile 1320 Laser System (K032459), the New Star Lasers CoolTouch 3, CT3, and II Lasers (K031184, K031954, and K030453), the New Star Lasers CoolTouch II and CT3 Nd:YAG Lasers (K040131), the Cynosure TriStar Aesthetic Workstation (K033176), the predicate Venus I, EL and Vela Er:YAG lasers manufactured by Laserscope (K974896, K971843 and other Laserscope Er:YAG laser clearances), the predicate FriendlyLight Er:YAG Pulsed Laser manufactured by Innotech USA (K000023), and the predicate Sciton Profile-S and 3000 Er:YAG Laser Systems (K040005 & K010285).

The modified MSq Family of Lovely Light/Laser System and Delivery Devices and Accessories shares identical indications for use, and similar design features, and functional features, and thus are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 21 2004

MSq (M<sup>2</sup>)Ltd.  
c/o Ms. Anne C. Worden  
Regulatory Consultant  
3637 Bernal Avenue  
Pleasanton, California 94566

Re: K042000  
Trade/Device Name: Modified MSq Family of Lovely Light/Laser Systems,  
Delivery Devices and Accessories  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: September 23, 2004  
Received: September 24, 2004

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

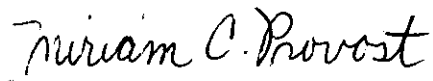
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Anne C. Worden

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Attachment 2 - Indications for Use Statement as Requested by FDA**  
**Modified MSq Family of Lovely Light/Laser Systems**

510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

**Indications for Use:**

The Lovely System models (Aria and Harmony) are intended for use in aesthetic, cosmetic, and surgical applications requiring the ablation, vaporization, excision, incision, and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of dermatology, general and plastic surgery, endoscopic/ laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, oral surgery, ophthalmology (skin around the eyes), orthopedics, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications, as follows:

**DERMATOLOGY AND PLASTIC SURGERY**

**Lovely I (Aria), Lovely II (Harmony) & Lovely III (TBD) Models:**

The Advanced Fluorescence Technology (AFT) 420-950 nm wavelengths are indicated for:

- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars and striae
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction
- Indicated for use on all skin types (Fitzpatrick I-IV), including tanned skin

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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Modified MSq Family of Lovely Light/Laser Systems

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**Attachment 2 - Indications for Use Statement as Requested by FDA**  
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Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

The UV Light source (290-380nm) is indicated for:

- The treatment of leukoderma, including vitiligo (acquired leukoderma).
- The treatment of psoriasis, atopic dermatitis (eczema), and seborrheic dermatitis.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The 1064 nm Nd:YAG lasers (Long Pulsed and Q-Switched) are indicated for treatment and clearance of:

- Benign vascular lesions such as, but not limited to treatment of:
  - ▷ Port wine stains
  - ▷ Hemangiomas
  - ▷ Warts
  - ▷ Superficial and deep telangiectasias (venulectasias)
  - ▷ Reticular veins (0.1-4.0 mm dia.) of the leg
  - ▷ Rosacea
  - ▷ Venus lake
  - ▷ Leg veins
  - ▷ Spider veins
  - ▷ Poikiloderma of Civatte
  - ▷ Angiomas

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

1064 nm Nd:YAG lasers (Long Pulsed and Q-Switched) – continued:

- Benign cutaneous lesions, such as:
  - Warts
  - Scars
  - Striae
  - Psoriasis
- Benign pigmented lesions such as, but not limited to:
  - Lentigos (age spots),
  - Solar lentigos (sun spots)
  - Café au lait macules
  - Seborrheic keratoses
  - Nevi and nevus of Ota
  - Chloasma
  - Verrucae
  - Skin tags
  - Keratoses
  - The removal of black, blue or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos)
  - Plaques

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

1064 nm Nd:YAG lasers (Long Pulsed and Q-Switched) – continued:

- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  - › Periocular wrinkles
  - › Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of:
  - › Acne scars
  - › Wrinkles
- Removal of unwanted hair, for stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Pseudofolliculitis barbae (PFB)
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar
- Indicated for use on all skin types (Fitzpatrick I-IV), including tanned skin

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

The 532 nm Frequency-Doubled (FD) Nd:YAG lasers (Long Pulsed and Q-Switched) are indicated for:

- Incision, excision, ablation, vaporization of soft tissue
- Tattoo removal
  - Light blue
  - Yellow
  - Red
  - Green
- Vascular lesions
  - Hemanigomas (Port wine stains/ birthmarks, and cavernous, cherry, and spider hemangiomas)
  - Angiomas (cherry, spider)
  - Telangiectasia
  - Spider nevi

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

532 nm Frequency-Doubled (FD) Nd:YAG lasers (Long Pulsed & Q-Switched) – continued:

- Benign pigmented lesions
  - › Café-au-lait (macules)
  - › Lentigines (senile and solar)
  - › Freckles (ephelides)
  - › Chloasma
  - › Nevi
  - › Nevus spillus
  - › Nevus of Ota
  - › Becker's nevi
- Other pigmented cutaneous lesions
  - › Verrucae
  - › Skin tags
  - › Keratoses
  - › Plaques

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known):     K042000    

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use:    - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

1320 nm Nd:YAG laser is indicated for the treatment of:

- Fine lines and wrinkles
- Periorbital wrinkles
- Perioral wrinkles
  
- Back acne
- Atrophic acne scars
- Mild to moderate inflammatory acne vulgaris

Prescription Use   ✓    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
Modified MSq Family of Lovely Light/Laser Systems - Continued**

510(k) Number (if known): **K042000**

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

2940 nm Er:YAG laser is indicated for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands):

- Skin resurfacing
- Treatment of wrinkles
- Epidermal nevi
- Telangiectasia
- Spider veins
- Actinic cheilitis
- Keloids
- Verrucae
- Skin tags
- Anal tags
- Keratoses
- Scar revision (including acne scars)
- Debulking benign tumors
- Debulking cysts
- Superficial skin lesions
- Diagnostic biopsies
- Decubitis ulcers

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

2940 nm Er:YAG laser – continued:

**GENERAL SURGERY:**

- Surgical incision/excision, vaporization, ablation, and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation, and/or vessel coagulation may be indicated

**GENITOURINARY:**

Treatment of:

- Lesions of the external genitalia, anus, penis, scrotum, and urethra (includes condyloma acuminata, giant perineal condyloma, and verrucous carcinoma), vulvar lesions, polyps, and familial polyps of the colon

**GYNECOLOGY:**

Treatment of:

- Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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**Attachment 2 - Indications for Use Statement as Requested by FDA  
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510(k) Number (if known): K042000

Device Name: Modified MSq Family of Lovely System Models: Lovely I (Aria), Lovely II (Harmony), and Lovely III (TBD)

Indications for Use: - Continued from previous page -

**DERMATOLOGY AND PLASTIC SURGERY - continued**

**Lovely II (Harmony) & Lovely III (TBD) Models:**

2940 nm Er:YAG laser – continued:

**ORAL/MAXILLOFACIAL:**

Treatment of:

- Benign oral tumors, oral and glossal lesions, and gingivectomy

**OTORHINOLARYNGOLOGY/ HEAD AND NECK (ENT):**

Treatment of:

- Ear, nose and throat lesions, polyps, cysts, hyperkeratosis
- Excision of carcinogenic tissue and oral leukoplakia

**OPHTHALMOLOGY:**

Treatment of:

- Soft tissue surrounding the eye and orbit

**PODIATRY:**

Treatment of:

- Warts, plantar verrucae, large mosaic verrucae
- Matrixectomy

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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